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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,339	01/25/2002	Teddy Kosoglou	CV01490K	1512

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
TRAVERS, RUSSELL S	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,339	KOSOGLOU ET AL.	
	Examiner	Art Unit	
	Russell Travers, J.D.,Ph.D	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *4-10,12-21,24-32,35-42,47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,11,22,23,33,34,43-46 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Election filed April 19, 2004 has been received and entered into the file.

Applicant's arguments filed April 19, 2004 have been fully considered but they are not deemed to be persuasive.

Claims 1-49 are presented for examination.

Applicant's election with traverse of group V, claims 1-11, 22-23, 33-34, 43-46 and 49 in Paper No. April 19, 2004 is acknowledged. The traversal is on the ground(s) that no undue burden would accrue. This is not found persuasive because to examine all presented distinct inventions would place an enormous burden on Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-10, 12-21, 24-32, 35-42 and 47-48 reading on non-elected subject matter are withdrawn from consideration.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth criteria defining those compounds which possess either "sterol absorption inhibition activity, or "cardiovascular agent" activity envisioned as useful for practicing the invention as claimed. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of those compounds envisioned as useful for practicing the instant invention which possess "sterol absorption inhibition activity, or "cardiovascular agent" activity examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples

are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all compounds envisioned as useful for practicing the invention as claimed which possess either "sterol absorption inhibition activity, or "cardiovascular agent", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-3, 11, 22-23, 33-34, 43-46 and 49 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-3, 11, 22-23, 33-34, 43-46 and 49 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 11, 22-23, 33-34, 43-46 and 49 are rendered indefinite by the phrases "sterol absorption inhibition activity, and "cardiovascular agent" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments possessing either "sterol absorption inhibition activity, or "cardiovascular agent" activity, envisioned as useful for practicing the invention as claimed, are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define

the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-3, 11, 22-23, 33-34 and 49 are rejected under 35 U.S.C. § 103 as being unpatentable over Rosenblum et al (996), and Chobanian et al.

Rosenblum et al teach the claimed ezetimibe compound as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form (see column 32, example 6). This medicament is taught as useful for reducing cholesterol

and treating arteriosclerosis (column 4, lines 50-66), at those levels herein envisioned (see column 20, line 21).

Chobanian et al teach the claimed captopril cardiovascular agent as old and well known in combination with various pharmaceutical carriers and excipients, in a dosage form (see abstract). This medicament is taught as useful for reducing cholesterol and treating arteriosclerosis, at those levels herein envisioned. Claims 1-3, 11, 22-23, 33-34 and 49, and the primary references, differ as to:

1) the concomitant employment of these medicaments, and

2) intended use for the compositions

It is generally considered prima facie obvious to combine two, or more, compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-arteriosclerosis agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claim 49 specifically requires a pharmaceutical composition for various therapeutic uses. Examiner cited prior art employed the claimed compounds for various vascular therapeutic uses, not specifically reciting other uses for the formulation.

Applicant's attention is drawn to In re Dillon, 16 USPQ2nd 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

Claims 43-46 are rejected under 35 U.S.C. § 103 as being unpatentable over Rosenblum et al (996), and Chobanian et al as set forth for claims 1-3, 11, 22-23, 33-34 and 49 above, in further view of Lelek et al, Myasnikov, and Schaarmann et al. Lelek et al teach the claimed omega 3 fatty acids, (linolenic acid) as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for reducing cholesterol and treating arteriosclerosis at those levels herein envisioned. Myasnikov teaches the claimed vitamin C as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for reducing cholesterol and treating arteriosclerosis, at those levels herein envisioned. Schaarmann et al teach the claimed soluble fiber as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form (see abstract). This medicament is taught as useful for positively influencing the ration of HDL to LDL ratio, and thereby constructively reducing the cholesterol level and treating arteriosclerosis.

Claims 43-46, and the primary references, differ as to:

1) the concomitant employment of these medicaments, and

It is generally considered prima facie obvious to combine two, or more, compounds each of which is taught by the prior art to be useful for the same purpose, in

order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-arteriosclerosis agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claims 43-46 specifically requires a pharmaceutical composition for various therapeutic uses. Examiner cited prior art employed the claimed compounds for various vascular therapeutic uses, not specifically reciting other uses for the formulation.

Applicant's attention is drawn to In re Dillon, 16 USPQ2nd 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D.,Ph.D whose telephone number is 571-272-0631. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Travers, J.D, Ph.D.
Primary Examiner
Art Unit 1617